

REMARKS

Status

Claims 85-111 were at issue in this Office Action. The present response does not add or cancel any claims. Accordingly, it is claims 85-111, as presently amended, which are at issue.

The Office Action

In the Office Action mailed November 30, 2010, claims 85-93, 99, 102-104 and 109-111 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent 4,669,477 of Ober taken in view of the published article of Lavigne. Claims 94, 95 and 97 were rejected under 35 U.S.C. §103 over Ober and Lavigne taken further in view of U.S. Patent 6,270,466 of Weinstein. Claim 96 was rejected under 35 U.S.C. §103 over the combination of Ober and Lavigne taken further in view of U.S. Patent 5,368,043 of Sunouchi.

Claims 98, 101, 105 and 106 were rejected under 35 U.S.C. §103 over the combination of Ober and Lavigne taken further in view of U.S. Patent Application Publication 2004/0068196 of Massicotte. Claim 100 was rejected under 35 U.S.C. §103 over Ober and Lavigne taken further in view of U.S. Patent 6,306,100 of Prass. Claims 107 and 108 were rejected under 35 U.S.C. §103 as being unpatentable over the combination of Ober, Lavigne, and Massicotte taken further in view of U.S. Patent 5,877,444 of Hine.

In addition, claim 99 was rejected under 35 U.S.C. §101 as being directed to nonstatutory subject matter.

Applicant thanks the Examiner for the Office Action and for the thorough explanation of the basis of the rejections.

The Present Invention

Applicant will briefly recapitulate the principles of the present invention so as to better explain how the claimed invention differs from the prior art. The present invention is directed to systems and methods which operate to detect the onset of bruxism and provide a feedback signal to a patient which enables the patient to control the condition. Systems for detecting and managing bruxism conditions are known in the prior art, including prior art made of record in this prosecution. The prior art systems all operate to measure jaw muscle activity and to provide a feedback signal if this activity is greater than a preset threshold. In the prior art systems, setting of the threshold is arbitrary insofar as the threshold is manually set to some selected value and then subsequently readjusted as necessary.

In contrast, the present invention carries out measurements and calculations which precisely set a threshold sensitivity value via a three-step process. In a first step of the process (1) a bite force signal is determined. In a second step (2) a signal indicative of a typical non-bite jaw motion is determined; and in a third step (3) a threshold is calculated on the basis of the two prior determinations such that the threshold represents a percentage (typically 3-20%) of the bite force, with the proviso that this threshold is greater than the maximum of the typical jaw muscle activity signal measured in step (2).

The three-step process of the present invention represents a significant and unexpected improvement over the prior art with regard to setting of the threshold. As detailed in the present application, the three-step process of the present invention assures that the feedback signal will be generated only in response to undesired jaw motion (bruxism) and not normally occurring jaw muscle activity. As will be detailed hereinbelow, the three-step method of the present invention is neither shown nor suggested in the prior art taken either singly or in combination.

The Rejections under 35 U.S.C. §103

None of the pending claims have been rejected with regard to novelty; however, all have been rejected as being obvious over the cited prior art. The basis for all of the obviousness-type rejections is the combination of U.S. Patent 4,669,477 of Ober and the publication of Lavigne. Claims 85-93, 99, 102-104 and 109-111 all stand rejected over this basic combination of references, while remaining claims are rejected as being obvious over the Ober and Lavigne prior art taken further in view of other references of record.

The Ober patent shows a very simple system typical of prior art approaches to managing bruxism. In this regard, the Ober patent shows a system which measures the level of jaw activity and provides a feedback signal if this level exceeds some manually input threshold. The setting of the threshold in Ober is accomplished through the use of a simple circuit which essentially sets the "sensitivity" of the system. Setting is accomplished on a manual, trial and error basis, and Ober does not detail any parameters for the establishment of the threshold. It is notable that the Ober system does not operate to determine bite force, typical non-bite jaw motion, nor does it calculate or otherwise establish any threshold which represents some percentage of the bite force with the proviso that this threshold is greater than the maximum of typical, non-biting, jaw muscle activity.

In this regard, the Examiner concedes, in the first full paragraph of page 4 of the Office Action, that Ober:

fails to explicitly disclose measuring a first level of muscle activity to generate a first signal; measuring a second level if [sic] muscle activity associated with a normally occurring jaw activity and generating a second signal; calculating a threshold that is less than 100% of the first level of muscular activity, but more than the second level of muscular activity

As such, the Examiner correctly recognizes that Ober does not show the steps of Applicant's claimed three-step process.

The Lavigne publication does not show or suggest any system or method for managing bruxism. It describes a clinical study performed to survey and analyze the sleep of a number of test subjects, and is primarily directed to the calibration of data collection systems.

As disclosed in page 547 of Lavigne, the patient performs a number of different jaw movements to allow for signal recognition and calibration of the amplification of an EMG signal. As particularly detailed at page 547, a patient carries out five distinct tasks so as to produce a specific EMG signal. The authors of the Lavigne publication are seeking to obtain patient-specific recordings of these particular jaw movements so as to be able to recognize these movements when analyzing data accumulated during sleep. Such analysis is carried out after sleep measurements are made, and hence while the patient is awake. There is no real-time analysis or assessment of data recorded during sleep, and there can be no implementation of Applicant's three-step process.

Lavigne in no way teaches setting of any threshold signal nor does Lavigne show or suggest that any data generated through the use of the Lavigne system and method could be used so as to control the sensitivity/threshold level of an apparatus for managing bruxism. All teaching in Lavigne is of the calibration of EMG amplification relating to the adjustment of the amplification signal provided from the EMG electrodes. Essentially, the Lavigne publication is teaching a method for collecting particular clinical data relating to jaw muscle activity. As acknowledged in Lavigne, electrical activity of the jaw muscles is weak and hence must be amplified for further processing. Lavigne recognizes that if this amplification is too strong, the signal is saturated and thereby difficult to analyze. Hence, the Lavigne publication proposes a

method for calibrating and adjusting EMG signal measurement and acquisition apparatus so as to avoid signal saturation (see the last line of the first paragraph of the right column at page 547).

In summary, teaching of Lavigne is of a calibration method involving measurements performed prior to sleep for the purpose of calibrating a signal amplifier. The method and apparatus of Lavigne do not relate to, disclose or suggest any set-up procedure for establishing a threshold used to control a system for managing bruxism in real time, much less with regard to a sleeping patient. In particular, Lavigne does not teach or suggest any need for measuring a first and a second level of jaw muscle activity and using acquired data to calculate and set a sensitivity threshold in a feedback system for managing bruxism.

The overall purpose of the clinical study of Lavigne was to accumulate data for purposes of diagnosing (but not controlling) bruxism. However, from the discussion on pages 550 and 551 of Lavigne, it is clear that this study does not actually provide any clear-cut diagnosis of bruxism. Lavigne provides cut-off criteria for the diagnosis of bruxism, but these cutoff criteria are based on the combination of a plurality of interrelated parameters and criteria. Lavigne further concludes (page 550, right column) that “cut-off values do not give simple yes or no outcomes. The cut-offs are not absolute numbers, and they should not be used without the overall patient evaluation.”

In rejecting the claims, the Examiner specifically acknowledges that Ober, while disclosing a system for managing bruxism, does not disclose any system which carries out Applicant's claimed three-step process; however, the Examiner contends that these specific steps are taught by Lavigne and that it would be obvious, in view of Lavigne, to modify the Ober system so as to approximate Applicant's claimed invention. Applicant respectfully disputes the propriety of this rejection. First of all, as discussed above, Lavigne does not disclose, either

explicitly or implicitly, any system which operates in a feedback mode to control bruxism. Lavigne merely provides a system for collecting data which is used as part of an "overall patient evaluation" in diagnosing bruxism. There is no teaching of any system operative in real time much less any system which provides an immediate feedback signal which ends an episode of bruxism. Given the purpose and operation of the Lavigne system, it is clear that there is no incentive to look to the teaching of Lavigne for any guidance as to systems for controlling bruxism. And, there is no expectation that adding any steps from Lavigne to a method or process of Ober would achieve the benefits of the present invention.

Even if the teachings of Ober and Lavigne were combined, they would not approximate the present invention. First of all, the two publications relate to very different aspects of bruxism, namely treatment with regard to Ober and clinical diagnosis/analysis in Lavigne. Secondly, neither of the two publications provide any knowledge or guidance relating to the calculation of the threshold (which is the essence of the present invention). In this regard, Ober merely teaches a manual, nonspecific setting of the threshold, and Lavigne does not provide any teaching at all relating to the need for, or means for, setting a threshold.

Thus, the Ober and Lavigne publications taken either singly or in combination do not disclose any anti-bruxism device which implements Applicant's claimed three-step process. Therefore, all claims are nonobvious in view of these two prior art references taken either singly or in combination with further references.

As noted above, various of the dependent claims have been rejected over the base references of Ober and Lavigne taken further in view of secondary references. Given the very clear inapplicability of the base rejection, all further rejections based upon secondary art are likewise overcome.

Reconsideration and withdrawal of these rejections is respectfully requested.

The Rejection under 35 U.S.C. §101

Claim 99 was rejected under 35 U.S.C. §101 as being directed to nonstatutory subject matter. Specifically, claim 99 refers to storage of data in an “associated memory”. As the Examiner states in section 1 of the Office Action at page 2, the current claim language does not limit the type of memory to that of a non-transitory memory, and therefore can be reasonably interpreted to also include the use of transitory types of memory, including a signal. The Examiner further comments that in order for the “associated memory” to be considered statutory it must be limited to a non-transitory memory.

Applicant thanks the Examiner for pointing out this problem, and by the present response has amended claim 99 to refer to a non-transitory memory. The specification as originally filed makes very clear that the memory utilized in the method and apparatus of the present invention is a non-transitory memory and includes extensive teaching of the use of non-transitory memory storage. For example, Figure 9 shows a system in which signals can be stored in semiconductor memory such as a flash memory shown at reference numeral 88. Further teaching is found in the specification, for example at paragraphs [0144]-[0145]. Likewise, paragraph [0134] specifically teaches that data can be stored in the apparatus in “non-volatile storage means”. Therefore, this amendment finds full support in the specification and drawings as originally filed.

Conclusion

In view of the amendments and remarks presented herein, Applicant respectfully submits that all rejections are overcome and the application is in condition for allowance. Any questions, comments, or suggestions which the Examiner may have should be directed to the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

Dated:

Respectfully submitted,

By

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